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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,424	07/22/2005	Klaus Henning	09600-00028-US	6261

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WILMINGTON, DE 19899

EXAMINER
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OLSON, ERIC

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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06/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,424	<b>Applicant(s)</b> HENNING, KLAUS	
	<b>Examiner</b> Eric S. Olson	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>February 14, 2005</u> . | 6) <input type="checkbox"/> Other: _____  |

### **Detailed Action**

This application is a national stage application of PCT/EP03/08411, filed July 30, 2003. Claims 1-13 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted February 14, 2005 is acknowledged wherein claims 12 and 13 are amended.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on August 16, 2002. It is noted, however, that applicant has not filed an English translation of the foreign application as required by 35 U.S.C. 119(b). In the absence of an English translation of the foreign priority document, the effective filing date of this application is July 30, 2003.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are drawn to a composition comprising a starch and "conventional additions." It is not clear from the claims or the specification what compounds are considered to be conventional additions for a dialysis solution or a plasma expander. Although pp. 9-10 of the specification suggest certain

examples of conventional additions, these examples are not in any way limiting and therefore do not serve to clearly and distinctly define the scope of the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sommermeyer et al. '207 (US patent publication 2004/0157207, patent application 10/486943, cited in PTO-1449, published as WO03/018639 on March 6, 2003, and as DE101-41-099.9 on July 23, 2002, copies of WO03/018639 and DE101-41-099.9 included with PTO-892) Sommermeyer et al. '207 discloses a highly branched starch that has improved breakdown properties for use in medical applications. (p. 1, paragraphs 0012-0014) In a particular preferred embodiment the degree of branching is 11-16 or 13-16%. (p. 2, paragraphs 0020-0021) A preferred molecular weight of 90000-300000, preferably 120000-250000, is disclosed for use as a plasma expander. (p. 2, paragraphs 0023-0025) Thus this hyperbranched, unsubstituted starch falls within the limitations of instant claims 1, 3, 5, 11, and 13, anticipating these claims.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Note that, as none of the priority documents for the instant application or for Sommermeyer et al. '207 are available in English, the effective filing date of the present application is July 30, 2003. Sommermeyer et al. '207 is equivalent to WO03/018639, published in German on March 6, 2003, and DE101-41-099.9, published on July 23, 2002.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-8, 11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommermeyer et al. (US patent 5218108, cited in PTO-1449, herein referred to as Sommermeyer et al. '108) in view of Antrim. (US patent publication 2002/0065410, patent application 09/725990, cited in PTO-1449) Sommermeyer et al. '108 discloses a hydroxylethyl starch having properties suitable for use as a plasma expander. (column 3, lines 25-62) In particular, an embodiment is disclosed having a mean molecular weight of 234000, a molar hydroxyethyl substitution degree of 0.26, and a C2-C6 ratio of 9.34. (column 5, lines 18-26) Also, claim 2 claims a starch with a

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mW of 80000-400000, a substitution degree of 0.2-0.4, and a C2/C6 ratio of 8-20.

Sommermeier et al. '108 does not disclose such a starch also having a degree of branching in the range of 8-20 mol %.

Antrim discloses a highly branched starch that is more stable in solution, and thus less liable to aggregate, haze, or precipitate. (p. 1, paragraphs 0006, 0007, and 00010) In a particular preferred embodiment the degree of branching is 8-10% or greater than 10%. (p. 2, paragraph 0012)

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the hydroxylethyl starch of Sommermeier et al. '108 with a degree of branching of 8-10% or greater, up to 20%, and a C2/C6 ratio of 8-9, and to use it as a plasma expander. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Antrim discloses that highly branched starches are more stable in solution, and thus more useful for a wide variety of applications. One of ordinary skill in the art would reasonably have expected success because the modifications described by Sommermeier et al. '108 can be made to a variety of starches. With regard to the C2/C6 ratio, when the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Thus the invention taken as a whole is *prima facie* obvious.

Claims 1-4, 6-8, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommermeyer et al. (US patent 6284140, cited in PTO-1449, herein referred to as Sommermeyer et al. '140) in view of Antrim. (US patent publication 2002/0065410, patent application 09/725990, cited in PTO-1449) Sommermeyer et al. '140 discloses a dialysis solution containing a hydroxylethyl starch having a molecular weight of 10000-150000, preferably 10000-55000, more preferably 20000-29000, most preferably 29000, a molar degree of substitution of 0.10-0.24, and a C2/C6 ratio of 8-25. (column 2, lines 10-38) This solution is stable for long periods of time and does not disturb residual kidney function. (column 4, lines 37-50) Sommermeyer et al. '140 does not disclose such a starch having a degree of branching of 8-20% or a C2/C6 ratio of 8-9.

Antrim discloses a highly branched starch that is more stable in solution, and thus less liable to aggregate, haze, or precipitate. (p. 1, paragraphs 0006, 0007, and 00010) In a particular preferred embodiment the degree of branching is 8-10% or greater than 10%. (p. 2, paragraph 0012)

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the hydroxylethyl starch of Sommermeyer et al. '140 with a degree of branching of 8-10% or greater, up to 20%, and a C2/C6 ratio of 8-9, and to use it in a peritoneal dialysis solution. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Antrim discloses that highly branched starches are more stable in solution, and thus more useful for a wide variety of applications. In particular, they are less likely to precipitate or otherwise display

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undesirable physical properties in the peritoneal cavity during long dwell times. One of ordinary skill in the art would reasonably have expected success because the modifications described by Sommermeyer et al. '140 can be made to a variety of starches. With regard to the C2/C6 ratio, when the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Thus the invention taken as a whole is *prima facie* obvious.

Claims 1-3, 5-8, 11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommermeyer et al. (US patent 5218108, cited in PTO-1449, herein referred to as Sommermeyer et al. '108) in view of Sommermeyer et al. '207 (US patent publication 2004/0157207, patent application 10/486943, cited in PTO-1449) Sommermeyer et al. '108 discloses a hydroxylethyl starch having properties suitable for use as a plasma expander. (column 3, lines 25-62) In particular, an embodiment is disclosed having a mean molecular weight of 234000, a molar hydroxyethyl substitution degree of 0.26, and a C2-C6 ratio of 9.34. (column 5, lines 18-26) Also, claim 2 claims a starch with a mW of 80000-400000, a substitution degree of 0.2-0.4, and a C2/C6 ratio of 8-20. Sommermeyer et al. '108 does not disclose such a starch also having a degree of branching in the range of 8-20 mol %.

Sommermeyer et al. '207 discloses a highly branched starch that has improved breakdown properties for use in medical applications. (p. 1, paragraphs 0012-0014) In a



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particular preferred embodiment the degree of branching is 11-16 or 13-16%. (p. 2, paragraphs 0020-0021) A preferred molecular weight of 90000-300000, preferably 120000-250000, is disclosed for use as a plasma expander. (p. 2, paragraphs 0023-0025) The hyperbranched amylopectins can be derivatized as hydroxylethyl or hydroxypropyl amylopectins. (p. 2, paragraph 0029)

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the hydroxylethyl starch of Sommermeyer et al. '108 with a degree of branching of 8-10% or greater, up to 20%, and a C2/C6 ratio of 8-9, and to use it as a plasma expander. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Sommermeyer et al. '207 discloses that highly branched starches have better breakdown properties, and are thus more useful as plasma expanders. One of ordinary skill in the art would reasonably have expected success because the modifications described by Sommermeyer et al. '108 can be made to a variety of starches. With regard to the C2/C6 ratio, when the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Thus the invention taken as a whole is *prima facie* obvious.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-4, 6-8, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommermeyer et al. (US patent 6284140, cited in PTO-1449, herein referred to as Sommermeyer et al. '140) in view of Sommermeyer et al. '207 (US patent publication 2004/0157207, patent application 10/486943, cited in PTO-1449) Sommermeyer et al. '140 discloses a dialysis solution containing a hydroxylethyl starch having a molecular weight of 10000-150000, preferably 10000-55000, more preferably 20000-29000, most preferably 29000, a molar degree of substitution of 0.10-0.24, and a C2/C6 ratio of 8-25. (column 2, lines 10-38) This solution is stable for long periods of time and does not disturb residual kidney function. (column 4, lines 37-50) Sommermeyer et al. '140 does not disclose such a starch having a degree of branching of 8-20% or a C2/C6 ratio of 8-9.

Sommermeyer et al. '207 discloses a highly branched starch that has improved breakdown properties for use in medical applications. (p. 1, paragraphs 0012-0014) In a particular preferred embodiment the degree of branching is 11-16 or 13-16%. (p. 2, paragraphs 0020-0021) A preferred molecular weight of 90000-300000, preferably 120000-250000, is disclosed for use as a plasma expander. (p. 2, paragraphs 0023-0025) The hyperbranched amylopectins can be derivatized as hydroxylethyl or hydroxypropyl amylopectins. (p. 2, paragraph 0029) Apart from use as a plasma volume expander, these starches can also be used in any other therapeutic application where standard hydroxyethylcellulose is used. (p. 3, paragraph 0032)

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the hydroxylethyl starch of Sommermeyer et al. '140 with a degree of branching of 8-10% or greater, up to 20%, and a C2/C6 ratio of 8-9, and to use it in a peritoneal dialysis solution. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Sommermeyer et al. '207 discloses that highly branched starches have better breakdown properties, and are thus more useful for use *in vivo*. In particular, they are less likely to precipitate or otherwise display undesirable physical properties in the peritoneal cavity during long dwell times. One of ordinary skill in the art would reasonably have expected success because the modifications described by Sommermeyer et al. '140 can be made to a variety of starches. With regard to the C2/C6 ratio, when the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Thus the invention taken as a whole is *prima facie* obvious.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of Sommermeyer et al. '207, Sommermeyer et al. '108 in view of Antrim, Sommermeyer et al. '140 in view of Antrim, Sommermeyer et al. '108 in view of Sommermeyer et al. '207,

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or Sommermeyer et al. '140 in view of Sommermeyer et al. '207, as applied to claims 1-4, 6-8, and 10-13 above, and further in view of Naggi et al. (PCT international publication WO00/33851, reference included with PTO-1449) the disclosures of Sommermeyer et al. '207, Sommermeyer et al. '108 in view of Antrim, Sommermeyer et al. '140 in view of Antrim, Sommermeyer et al. '108 in view of Sommermeyer et al. '207, and Sommermeyer et al. '140 in view of Sommermeyer et al. '207 are discussed above. None of these references disclose a starch in which the reducing end has been inactivated by oxidation or reduction.

Naggi et al. discloses a sterilized peritoneal dialysis solution comprising a starch in which the reducing end has been inactivated by oxidation or reduction. (pp. 4-5) These starches have the advantage that they are stable under autoclaving and steam sterilization conditions. (p. 10, lines 15-18) This property is useful because it allows for high-temperature sterilization of the starch solutions without the production of formaldehyde. (p. 3, lines 14-24)

It would have been obvious to one of ordinary skill in the art at the time of the invention to oxidatively or reductively modify the reducing ends of the starches of any of the aforementioned references. One of ordinary skill in the art would have been motivated to modify the invention in this way because Naggi et al. discloses that doing so allows the starch to be autoclaved without forming toxic degradation products such as formaldehyde. One of ordinary skill in the art would reasonably have expected success because oxidations and reductions are simple chemical transformations that can reasonably be applied to a wide number of starches using only simple and routine

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chemical procedures, and because the techniques of Naggi et al. are reasonably expected to be applicable to any polysaccharide with a reducing end.

Thus the invention taken as a whole is *prima facie* obvious.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5, and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6, and 7 of copending Application No. 10/486943. (US patent publication 2004/0157207, cited in PTO-1449, herein referred to as Sommermeyer et al. '207) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2, 6, and 7 of Sommermeyer et al. '207 anticipate the instant claims. In particular,

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claims 1, 6, and 7 of Sommermeyer et al. '207 claim a hyperbranched amylopectin having the same characteristics (MW and degree of branching) as the one used in the instant invention. Claim 2 of Sommermeyer et al. '207 is drawn to the use of said amylopectin as a plasma volume expander. Thus the claimed invention is anticipated by Sommermeyer et al. '207.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

No claims are allowed in this application.

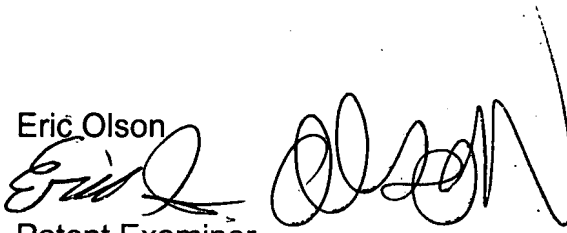
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson

  
Patent Examiner  
AU 1623  
5/18/07

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